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10/586,489	07/20/2006	Ochayi C. Agboh	978-125	4197

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EXAMINER	
BUCKLEY, AUDREA	
ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/586,489	AGBOH ET AL.	
	Examiner	Art Unit	
	AUDREA BUCKLEY	4131	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,8-17 and 21-38* is/are pending in the application.

4a) Of the above claim(s) *1-5, 8-17, and 37-38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/20/2006, 6/26/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of Group II, claims 21-36, in the reply filed on June 26, 2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-20 and 37-42 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected process and a nonelected wound dressing, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on June 26, 2009.

The requirement is still deemed proper and is therefore made FINAL.

Priority

This application, filed July 20, 2006 claims priority to PCT/GB2005/000261, filed 01/27/2005. Instant claims 1-20 and 37-42 are supported in the specification from PCT/GB2005/000261.

Acknowledgment is made of applicant's claim for priority under 35 U.S.C. 119(a)-(d) based upon an application filed in the United Kingdom on 01/28/2004. Accordingly, these papers have been placed of record in the file.

Information Disclosure Statement

The information disclosure statements (IDS) submitted on July 20, 2006 and June 26, 2009 were filed on and before the mailing date of the application on July 20, 2006. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 21, 22, 26-28, 32, and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Burrell *et al.* (US 2001/0055622).

Regarding claim 21, Burrell *et al.* teach antimicrobial materials which provide an effective and sustainable antimicrobial effect through the implementation of antimicrobial metals into a polymeric matrix, among other formulations (page 1, column 1, [0001], in particular; see also, page 5, column 2, [0078]).

As to claim 22, Burrell *et al.* teach a formulation into which the antimicrobial metals can be in the form of a continuous coating (page 1, column 2, [0020]).

As to claim 26, Burrell *et al.* teach metal nanoparticles which exhibit antimicrobial properties (page 1, column 2, [0019]). As to claim 27, Burrell *et al.* teach antimicrobial metal identities as Ag, Au, Pt, Pd, Ir, Sn, Cu, Sb, Bi, Zn, or alloys or compounds thereof (page 9, claim 14). As to claim 28, silver is listed as a metal identity comprising the nanocrystalline coating or powder disclosed (page 9, claim 14).

As to claim 32, Burrell *et al.* disclose a polymer matrix identity which can be comprised of synthetic bioabsorbable polymers or of naturally derived polymers (page 1, [0010]-[0013]). As to claim 33, alginate is named among the polymers acceptable for use in the preferred embodiments (page 1, [0013]).

Since the content and limitations of instant claims 21, 22, 26-28, 32, and 33 are taught in the Burrell *et al.* reference, these claims are rejected as being anticipated by Burrell *et al.*

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 21, 23-25, and 29-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burrell *et al.* (US 2001/0055622).

Regarding claim 21, Burrell *et al.* teach antimicrobial materials which provide an effective and sustainable antimicrobial effect through the implementation of antimicrobial metals into a polymeric matrix, among other formulations (page 1, column 1, [0001], in particular; see also, page 5, column 2, [0078]). Therefore, claim 21 is anticipated by the Burrell reference.

Regarding claim 23, which limits the metal nanoparticles to those having a size less than 500 nm, Burrell *et al.* teach metal nanoparticles to those having a size preferably less than 100 nm (page 1, column 2, [0020]). Although the range of metal particles taught by Burrell *et al.* remains more narrow than that instantly claimed, the disclosure of the instant invention demonstrates no embodiments lying between the previously disclosed preferred maximum of 100 nm and the instantly claimed maxima of 500 nm. Further, no advantages of the more broadly claimed instant range are given. Also, one of ordinary skill in the art at the time the invention was made would have been motivated to perform routine optimization procedure to implement values around the previously known range. MPEP 2144.05 addresses routine optimization procedures as they relate to patentability:

> "Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (Claimed process which was performed at a temperature

> between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.)."

For these reasons, one of ordinary skill in the art at the time the invention was made would have found the particular size limitation as outlined in instant claim 23 to have been *prima facie* obvious in view of the prior particulate limitations as taught by Burrell *et al.* and in view of routine scientific optimization protocol.

As to claim 24, Burrell *et al.* teach that the antimicrobial metals are present in particulate or crystalline size of less than 100 nm (page 1, column 2, [0020]-[0021]). As to claim 25, which limits the metal particle size to a value between 20 and 100 nm, Burrell *et al.* previously teach metal particles less than 100 nm and most preferably less than 20 nm (page 1, column 2, [0020]-[0021]). Although this prior teaching differs from that of the instant claim with respect to the desirable particle size minimum, one of ordinary skill in the art at the time the invention was made would have been motivated to perform routine optimization procedure about the previously taught size limitation values. See MPEP 2144.05 for routine optimization procedure as it relates to patentability.

Regarding claim 29 which limits the fiber diameter, Burrell *et al.* teach analogous art which limits a polymer film coating containing antimicrobial metals to a thickness of 500 microns (page 9, claim 7). Also, Burrell *et al.* teach coating fibers as an acceptable embodiment of the invention (page 5, [0078]).

Burrell *et al.*, however, do not teach a fiber diameter limitation.

However, one of ordinary skill in the art at the time the invention was made would have been motivated to utilize ordinary skill in order to extract the inventive concept of the prior art which teaches antimicrobial coating thickness limitations to the fiber diameter limitation of 500 microns as instantly claimed.

Likewise and as to claims 30 and 31, Burrell *et al.* teach an antimicrobial coating thickness of preferably less than 500 nm and very fine grained, with a powder particle size of preferably less than 100 micrometers or preferably less than 40 micrometers (page 1, [0021]) for powder formulations analogous to the art instantly disclosed. Although this prior teaching differs from that of the instant claim with respect to the fiber diameter size limitations, one of ordinary skill in the art at the time the invention was made would have been motivated to perform routine optimization procedure about the previously taught limitation values. See MPEP 2144.05 for routine optimization procedure as it relates to patentability.

Therefore, one of ordinary skill in the art at the time the invention was made would have found the routine optimization procedures based on the teachings of Burrell *et al.* as they relate to metal particle size limitations and fiber size limitations as instantly claimed to have rendered the content of instant

claims 21, 23-25, and 29-31 to have been *prima facie* obvious as these teachings relate to the analogous compositions comprising a polymer matrix and antimicrobial, nanoparticulate metal inclusion.

Claim 32-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burrell *et al.* (US 2001/0055622) in view of Qin *et al.* (WO02/36866).

As to claim 32, Burrell *et al.* disclose a polymer matrix identity which can be comprised of synthetic bioabsorbable polymers or of naturally derived polymers (page 1, [0010]-[0013]). As to claim 33, alginate is named among the polymers acceptable for use in the preferred embodiments (page 1, [0013]). So, claims 32 and 33 are rendered *prima facie* obvious as discussed above.

Regarding claim 34, Burrell *et al.* do not teach a quantitative limitation of silver presence in the polymer matrix comprising alginate.

However, Qin *et al.* teach polysaccharide fibers having antimicrobial properties wherein these fibers comprise alginate as well as antimicrobial metal containing particles which are present in a concentration between 0.1 and 2% w/w (page 21, claims 1 and 7).

Since the art taught by Qin *et al.* clearly is analogous with the art taught by Burrell *et al.*, one of ordinary skill in the art at the time the invention was made would have been motivated to implement the quantitative anti-microbial silver-containing agent presence as disclosed by Qin *et al.* into a formulation such as

that taught by Burrell *et al.* Further, one of ordinary skill in the art reasonably would have expected success from this implementation.

On account of these prior teachings and the reasonably expected success upon combination as described above, one of ordinary skill in the art at the time the invention was made would have found the content of instant claim 34 to have been *prima facie* obvious.

Claims 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Burrell *et al.* (US 2001/0055622) in view of Dresdner, Jr. *et al.* (US 5,357,636 A).

Regarding claim 35, Burrell *et al.* do not explicitly teach polyacrylonitrile as the synthetic polymer identity.

However, Dresdner, Jr. *et al.* teach polyacrylonitrile as the synthetic polymer identity in a flexible protective medical glove containing an antiseptic composition (column 80, line 55) where this material presents the desired structural properties for the functional application disclosed.

One of ordinary skill in the art at the time the invention was made would have found the glove materials as taught by Dresdner, Jr. *et al.* to have been art analogous to that of Burell *et al.,* as these disclosures both teach antimicrobial implements into polymeric scaffolds. On account of the analogous art, one of ordinary skill in the art at the time the invention was made would have been motivated to combine features of these references, such as the polyacrylonitrile

synthetic polymer identity as taught by Dresdner, Jr. *et al.* into the general synthetic polymer identity taught by Burrell *et al.*

Therefore, one of ordinary skill in the art at the time the invention was made would have found the implementation of polyacrylonitrile as the synthetic polymer component of an antimicrobial formulation to have been *prima facie* obvious in view of the teachings of Burrell *et al.* and Dresdner, Jr. *et al.*

Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Burrell *et al.* (US 2001/0055622) and Qin *et al.* (WO02/36866) as applied to claims 21 and 32-34 above, and further in view of Dresdner, Jr. *et al.* (US 5,357,636 A).

Neither Burrell *et al.* nor Qin *et al.* explicitly teach polyacrylonitrile as the synthetic polymer identity in a quantity of 0.1 to 2% presence by weight.

Regarding claim 36, one of ordinary skill in the art at the time the invention was made would have been motivated to combine polyacrylonitrile polymer matrix with a quantity of silver where the quantity of silver overlaps with the effective quantity of silver agent as previously disclosed in the analogous prior art. Specifically, Qin *et al.* teach polysaccharide fibers having antimicrobial properties wherein these fibers comprise alginate as well as antimicrobial metal containing particles which are present in a concentration between 0.1 and 2% w/w (page 21, claims 1 and 7). Although this previously disclosed range of analogous component in an analogous composition does not exactly match that of the instant claim, one of ordinary skill in the art would have found adjustment

about this previously known range to have been well within the routine of optimization protocol, a procedure which lacks patentable weight (see MPEP 2144.05).

One of ordinary skill in the art at the time the invention was made would have found the glove materials as taught by Dresdner, Jr. *et al.* to have been art analogous to that of Burell *et al.* and Qin *et al.*, as these three disclosures all teach antimicrobial implements into polymeric scaffolds. On account of the analogous art, one of ordinary skill in the art at the time the invention was made would have been motivated to combine features of these references, such as the polyacrylonitrile synthetic polymer identity as taught by Dresdner, Jr. *et al.* into the general synthetic polymer identity taught by Burrell *et al.*

Therefore, one of ordinary skill in the art at the time the invention was made would have found the implementation of polyacrylonitrile as the synthetic polymer component of an antimicrobial formulation to have been *prima facie* obvious in view of the teachings of Burrell *et al.*, Qin *et al.*, and Dresdner, Jr. *et al.*

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AUDREA BUCKLEY whose telephone number is (571)270-1336. The examiner can normally be reached on Monday-Thursday 7:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patrick Nolan can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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